200 West Ohio Avenue
Dover, OH 44622
(330) 364-0981

AUG 9 2013

Summary of Safety and Effectiveness

Sponsor:	Zimmer Surgical, Inc. 200 West Ohio Avenue Dover, OH 44622
Contact Person:	Allison Scott, RAC Regulatory Affairs Consultant Telephone: (317) 569-9500 x106 Fax: (317) 569-9520
Date:	November 16, 2012
Trade Name:	*Zimmer*® *A.T.S.* ® 4000TS Tourniquet System
Product Code / Device:	KCY - Pneumatic tourniquet
Regulation Number / Description:	21 CFR § 878.5910 - Pneumatic tourniquet
Predicate Device:	*Zimmer*® *A.T.S.*® 3000 Automatic Tourniquet System, K050411, cleared 09/02/2005
Device Description:	The *Zimmer A.T.S.* 4000TS Tourniquet System is a non-sterile device intended to be used by qualified medical professionals to temporarily occlude blood flow in a patient's extremities during surgical procedures on those extremities. The system consists of the *A.T.S.* 4000TS control unit that is coupled to the patient with the applied part (inflatable pneumatic tourniquet cuff) via the connecting tubing. The tourniquet cuff is applied to the patient prior to the procedure beginning. The connecting tubing is attached to the inflatable tourniquet cuff and plugged into the *A.T.S.* 4000TS's connector ports.

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Intended Use:	The *A.T.S.* 4000TS Automatic Tourniquet System is intended to be used by qualified medical professionals to temporarily occlude blood flow in a patient's extremities during surgical procedures on those extremities. Tourniquets have been found useful in producing a bloodless operation field in surgical procedures involving the extremities including: Reduction of certain fractures, Kirschner wire removal, Tumor and cyst excisions, Subcutaneous fasciotomy, Nerve injuries, Tendon repair, Bone grafts, Total wrist joint replacement, Replacement of joints in the fingers, Knee joint replacements, Amputations, Replantations
Comparison to Predicate Device:	The *Zimmer A.T.S.* 4000TS Automatic Tourniquet System is substantially equivalent to other legally marketed tourniquet systems, specifically the *Zimmer A.T.S.* 3000 Tourniquet System in that the devices are similar in design, materials, and indications for use. Additionally, the LOP feature of the *Zimmer A.T.S.* 4000TS Automatic Tourniquet System is substantially equivalent to the *Zimmer A.T.S.* 3000 Tourniquet System.
Performance Data (Nonclinical and/or Clinical):	Non-Clinical Performance and Conclusions: During the development process of the *AT.S.* 4000TS, the following testing was completed: Electrical safety and Environmental testing in accordance with IEC 60601-1, 60601-1-2, 60601-1-8; Software and device development was conducted in accordance with requirements of IEC 62304:2006 and AAMI/ANSI HE-75:2009; Device Usability testing was conducted in accordance with requirements of IEC 60601-1-6 and IEC 62366:2007, and Hardware and Software testing, including validation. All tests passed according to predetermined acceptance criteria. Clinical Performance and Conclusions: Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 9, 2013

Allison Scott, RAC
Regulatory, Affairs Consultant
Zimmer Incorporated
9001 Wesleyan Road, Suite 200
Indianapolis, Indiana 46268

Re: K123553
Trade Device Name: Zimmer® A.T.S.® 4000TS Automatic Tourniquet System
Regulation Number: 21 CFR 878.5910
Regulation Name: Pneumatic tourniquet
Regulation Class: Class I
Product Code: KCY
Dated: June 27, 2013
Received: July 3, 2012

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

Zimmer® A.T.S. ® 4000TS Tourniquet System

Indications for Use:

The *A.T.S.* 4000TS Tourniquet System is intended to be used by qualified medical professionals to temporarily occlude blood flow in a patient's extremities during surgical procedures on those extremities. Tourniquets have been found useful in producing a bloodless operation field in surgical procedures involving the extremities including:

Reduction of certain fractures

Kirschner wire removal

Tumor and cyst excisions

Subcutaneous fasciotomy

Nerve injuries

Tendon repair

Bone grafts

Total wrist joint replacement

Replacement of joints in the fingers

Knee joint replacements

Amputations

Replantations

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DSD—Division Sign-Off
Division of Surgical Devices
510(k) Number: K123553

Joshua C. Nipper -S